

**Remarks/Arguments:**

Claims 7-16 are pending and have been rejected.

**Claim Rejections under 35 USC § 101**

Claims 7, 13, and 16 are rejected as being directed toward non-statutory subject matter for positively reciting portions of the body. Claims 7 and 13 have been amended to indicate that the device is "sized to be" in a specific relationship to the body, as previously suggested by the examiner for overcoming similar rejections. Claim 16 has been amended to recite dimensions of the device, rather than dimensions of the body.

**Claim rejections in light of Kugler**

Claim 7-16 are rejected under 35 USC 102(e) as anticipated by, or in the alternative, under 35 U.S.C. 103(a) as obvious over, Kugler et al. (U.S. Pat. No. 6,129,756). In the Response to Arguments, the Office Action indicates that the arguments submitted by the applicant distinguishing the claimed transition region from this reference were found not persuasive, in part because "the same flare will appear conical if stretched and pulled taut upon anchoring, and will appear concave, trumpet shaped if left loose and anchored at a more proximal position in the lumen." The independent claims have been amended to recite that the trumpet-shaped, concave transition portion extending from the second diameter to the third diameter has "*a curved slope when viewed in longitudinal section in a non-deployed configuration.*" The applicant respectfully submits that this clarification distinguishes the claimed invention from Kugler.

Kugler does not teach or suggest such a transition portion having a curved slope when viewed in longitudinal section in a non-deployed configuration. Kugler only depicts a conical transition portion (which has a linear, non-curved slope when viewed in longitudinal section) in either the deployed or non-deployed configurations shown in the figures. Kugler nowhere discusses the actual shape of this portion in either configuration. The amended claim renders moot the position taken in the Office Action that the appearance of the flare is dependent upon the way in which it is stretched when deployed, because now the claim recites the structure of the flare in the non-deployed configuration.

In the Response to Arguments, the Office Action also raises the issue that there is no reference in the specification that there is an advantage of one shape over the other. Neither an applicant's arguments nor evidence traversing an obviousness rejection need be contained within the specification. The PTO may not disregard the evidence and arguments made by an applicant in response to an obviousness rejection by finding an applicant's arguments "unpersuasive" on the grounds that the advantage is not disclosed in the application. *In re Chu*, 36 USPQ2d 1089, 1095 (Fed. Cir. 1995) (reversing PTO's rejection of improvement as "merely an obvious design choice"). To require evidence and argument that something is not a matter of design choice in the specification would be to require patent applicants "to divine the rejections the PTO will proffer when patent applications are filed." *Id.* at 1094.

A rejection of claims as an "obvious design choice" is precluded where the claimed structure and the function it performs are different from the prior art. *Id.* The claimed structure of the transition section in a non-deployed configuration is different than what is shown in Kugler. The function of the transition portion having the claimed curved slope, which

allows the transition to be made over a shorter length than in a conical transition, is also different than what is shown in Kugler.

The Office Action states that "the specification seems to point out that any flare shape, conical, concave trumpet shape, or otherwise, is sufficient for retaining the distal end in a lumen." In support of this position, the Office Action cites language from page 9 of the applicant's specification, which does not support the position taken in the Office Action at all. The cited passage from the specification refers to Fig. 4, which shows the curved-trumpet shaped transition portion, and Fig. 5, which shows the conical transition portion, and then notes that the *end portion* (not the transition region) "may have any shape provided that the end portion is sized and configured to be efficiently retained into the corresponding iliac artery." The statement in the specification explicitly and clearly refers only to the end portion, not to the transition portion. The applicant shows and describes two distinct embodiments for the transition portion -- a conical transition portion and a trumpet-shaped transition portion. The end portion (element 15 in Figs. 4 and 5) is attached to the transition portion (elements 17 and 18 in Figs. 4 and 5, respectively), but is structurally distinct from the transition portion. Accordingly, the shape of the end portion 15 is irrelevant to the structure of the transition portions 17 and 18. The fact that the applicant shows only two transition portion structures undercuts the position taken in the Office Action that the specification points out *any shape* is sufficient, because only two such shapes are disclosed for the transition portion. The Office Action has not cited any motivation to use a trumpet-shaped transition portion instead of a conical transition portion, except that which is found in the specification itself. This is impermissible hindsight.

#### **Claim rejections in light of Martin in view of Strecker**

Claims 7-9 and 11-16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Martin (U.S. Patent No. 5,575,817) in view of Strecker (U.S. Patent No. 5,405,378). In the Response to Arguments, the Office Action states that the Strecker reference is relied upon as a teaching for flaring ends of endoluminal prostheses in a trumpet shape. The applicant, however, does not claim flaring the *ends* of the prosthesis in a trumpet shape, but rather providing a trumpet-shaped *transition portion*.

The independent claims have been amended to recite a that the end portion has "a defined length," which further differentiates the claimed invention from Strecker. Strecker does not provide any figures to illustrate its description of a "trumpet-shaped expansion at the proximal end". Accordingly, those skilled in the art are left to merely imagine this trumpet-shaped expansion. The most logical frame of reference for such an imagined structure is the musical instrument from which the adjective "trumpet-shaped" derives its name. The musical instrument trumpet flares outwardly to a maximum diameter, but does not have a defined length at the maximum diameter. By contrast, the applicant claims a distinct and defined end portion having a length that is attached to the maximum diameter of the trumpet-shaped transition portion. Accordingly, Strecker fails to teach each and every limitation of the claimed invention. Nothing in Strecker suggests that the trumpet-shaped end portion can be used as a transition portion.

In fact, because the stated function of the expanded end in Strecker is to avoid the end slipping into a branch vessel, it would defeat the purpose of the device described in Strecker to have an end portion of any defined length at the maximum diameter, because that end portion would then likely extend into the branch vessel, which is precisely what the expanded end is supposed to help avoid. Where modification of the cited art would change a basic principle

upon which the disclosed device is designed to operate, the teachings of the references are not sufficient to render the claims obvious. See, e.g., *In re Ratti*, 270 F.2d 810, 123 USPQ 349 (CCPA 1959); MPEP 2143.01.

**Conclusions**

For all of the above reasons, the rejections under 35 U.S.C. §§ 101, 102, and 103 should all be withdrawn. Favorable action is earnestly solicited. The Examiner is invited to call the applicants' undersigned representative if any further amendment will expedite the prosecution of the application or if the Examiner has any suggestions or questions concerning the application or the present Response.

Respectfully submitted,

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